



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HF7-35 m3285n  
Food and Drug Administration  
Atlanta District Office  
purged DJW

60 8th Street, N.E.  
Atlanta, Georgia 30309

December 10, 1999

**VIA FEDERAL EXPRESS**

Tommy Fulcher, Owner  
Mike Fulcher, Owner  
Clayton Fulcher Seafood Company  
P.O. Box 300, Core Sound Road  
Atlantic, NC 28511

**Warning Letter**  
00-ATL-16

Dear Messrs. Fulcher:

On July 15-16, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 142 South Ferry Dock Road, Harkers Island, North Carolina. During that inspection, our investigator documented serious deviations from FDA's Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh shrimp and histamine-susceptible fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

You have failed to develop and implement written HACCP plans in accordance with 21 CFR 123.6, to address potential hazards associated with the seafood products processed and/or stored, including the presence of sulfiting agents in fresh shrimp, and histamine formation in histamine-susceptible fish. These deviations were previously brought to your attention in our letter of October 16, 1998.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

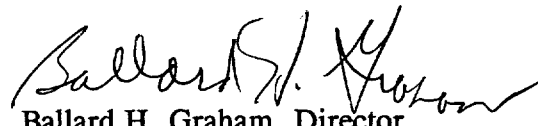
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you

will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

  
Ballard H. Graham, Director  
Atlanta District

cc: Clayton Fulcher Seafood Company  
c/o M. Bryan Yeomans, Manager  
465 Island Road  
Harkers Island, NC 28531